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CITIZEN PETITION TO PROVIDE CERTIFICATION TO CONGRESS
UNDER SECTION 804(l) OF CHAPTER VIII OF THE FEDERAL
FOOD, DRUG, AND COSMETICS ACT, AND TO
AUTHORIZE A PILOT PROGRAM FOR IMPORTATION OF
PRESCRIPTION DRUGS IN THE STATE OF ILLINOIS

Petitioner:

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on behalf of the State of Illinois

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Before the
Department of Health and Human Services
Food and Drug Administration
Washington, D.C.

In Re: Petition to Provide Certification)	
to Congress Under Section 804(l) of)	
Chapter VIII of the Federal Food,)	Docket No. _____
Drug and Cosmetics Act, and to)	
Authorize a Pilot Program for)	
Importation of Prescription Drugs)	
in the State of Illinois)	

CITIZEN PETITION

The undersigned, Governor Rod R. Blagojevich, by counsel, on behalf of the State of Illinois ("Illinois") hereby submits this petition under Section 804 of Chapter VIII of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), as amended by Section 1121 of the Medicare Prescription Drug and Modernization Act of 2003 (the "MPDM Act"), or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (the "Commissioner") under Chapter 21, Section 5.10 of the Code of Federal Regulations, to request the Commissioner to (1) provide a certification to Congress in accordance with Section 804(l) of the FFDCA to commence the provisions of Section 804 of the FFDCA; (2) amend Chapter 21, Section 203.10 of the Code of Federal Regulations, barring the reimportation of prescription drugs; (3) issue regulations permitting pharmacists and wholesalers to import and to reimport prescription drugs from Canada into the United States in accordance with Section 804(b) of the FFDCA; (4) in the alternative, issue regulations permitting pharmacists and wholesalers to import and to reimport prescription drugs from Canada into Illinois in accordance with Section 804(b) of the FFDCA, as a pilot program to test whether such importation and reimportation should be permitted nationwide; (5) in the alternative, issue regulations authorizing Illinois to establish a more limited pilot program for pharmacists and wholesalers to import prescription

drugs from Canada into Illinois for Illinois state employees and retirees in accordance with Section 804(b) of the FFDCA; (6) in the alternative, issue regulations granting to the residents of the United States a waiver of the prohibition of importation and reimportation of prescription drugs in accordance with Section 804(j) of the FFDCA, so that residents may import or reimport prescription drugs from Canada into the United States for personal use; (7) in the alternative, issue regulations granting to the residents of Illinois a waiver of the prohibition of importation and reimportation of prescription drugs in accordance with Section 804(j) of the FFDCA, so that residents may import or reimport prescription drugs from Canada into the United States for personal use, as a pilot program to test whether such a waiver should be granted nationwide; and (8) in the alternative, issue regulations granting to the residents of Illinois a waiver of the prohibition of importation and reimportation of prescription drugs in accordance with Section 804(j) of the FFDCA, so that Illinois residents may participate in a more limited pilot program for Illinois state employees and retirees to import or reimport prescription drugs from Canada into Illinois for personal use.

I. ACTION REQUESTED

A. Certification to Congress

Illinois requests that the Commissioner certify to Congress as follows: "The Commissioner of the Food and Drug Administration (the "Commissioner"), in accordance with the authority delegated to the Commissioner by the Secretary of Health and Human Services under Chapter 21, Section 5.10 of the Code of Federal Regulations, hereby certifies to Congress in accordance with Section 804(l) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), as amended by Section 1121 of the Medicare Prescription Drug and Modernization Act of 2003, that the implementation of Section 804 of the FFDCA will (A) pose no additional risk to the public's health and safety, and (B) result in a significant reduction in the cost of covered products

to the American consumer." This first request is a necessary prerequisite to the additional and alternative requests set forth in Section I.B through I.H of this Petition.

B. Amendment of 21 CFR § 203.10

Illinois requests that the Commissioner amend Chapter 21, Section 203.10 of the Code of Federal Regulations, which provides:

Section 203.10 Restrictions on reimportation.

No prescription drug or drug composed wholly or partly of insulin that was manufactured in a State and exported from the United States may be reimported by anyone other than its manufacturer, except that FDA may grant permission to a person other than the manufacturer to reimport a prescription drug or insulin-containing drug if it determines that such reimportation is required for emergency medical care.

Illinois requests that Section 203.10 be replaced with one of the three alternative regulations proposed in Sections I.C, I.D, and I.E of this Petition.

C. Issuance of Regulations Permitting Importation and Reimportation of Prescription Drugs from Canada into the United States

Illinois requests that the Commissioner consult with the United States Trade Representative and the Commissioner of Customs, in accordance with the requirements of Section 804(b) of the FFDCA and the authority delegated to the Commissioner under Chapter 21, Section 5.10 of the Code of Federal Regulations, and promulgate regulations permitting pharmacists and wholesalers to import and to reimport prescription drugs from Canada into the United States. Illinois proposes the following regulation in place of Chapter 21, Section 203.10 of the Code of Federal Regulations:

Section 203.10 Importation and reimportation.

(a) No prescription drug or drug composed wholly or partly of insulin that was manufactured in a State and exported from the United States may be reimported by anyone other than its manufacturer, except that FDA may grant permission to a person other than the manufacturer to reimport a prescription drug or insulin-containing drug if it determines that such reimportation is required for emergency medical care, and except as otherwise provided in this section.

(b) Pharmacists and wholesalers are permitted to import and to reimport prescription drugs from Canada into the United States under the conditions and restrictions set forth in this section.

(c) Each prescription drug imported or reimported under subsection (b) of this section must comply with section 505 of the Federal Food, Drug, and Cosmetic Act (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502 of the Federal Food, Drug, and Cosmetic Act, and with all other applicable requirements of the Federal Food, Drug, and Cosmetic Act relating to the safety and effectiveness of prescription drugs.

(d) Information and Records—

(1) Every importer of a prescription drug under subsection (b) of this section shall submit to the Food and Drug Administration the following information and documentation:

(A) The name and quantity of the active ingredient of the prescription drug.

(B) A description of the dosage form of the prescription drug.

(C) The date on which the prescription drug is shipped.

(D) The quantity of the prescription drug that is shipped.

(E) The point of origin and destination of the prescription drug.

(F) The price paid by the importer for the prescription drug.

(G) Documentation from the foreign seller specifying—

(i) the original source of the prescription drug; and

(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

(I) The name, address, telephone number, and professional license number (if any) of the importer.

(J) (i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

(III) (aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

(i) is approved for marketing in the United States and is not adulterated or misbranded; and

(ii) meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act.

(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

(2) The Food and Drug Administration shall maintain information and documentation submitted under paragraph (1) for such period of time as the Food and Drug Administration determines to be necessary, but for not less than one (1) year.

(e) Testing—

(1) The testing described in subparagraphs (J) and (L) of subsection (d)(1) of this section shall be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory.

(2) If the tests are conducted by the importer—

(A) information needed to—

(i) authenticate the prescription drug being tested; and

(ii) confirm that the labeling of the prescription drug complies with labeling requirements under the Federal Food, Drug, and Cosmetic Act

shall be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

(B) the information supplied under subparagraph (A) shall be kept in strict confidence and used only for purposes of testing under this section or otherwise complying with the Federal Food, Drug, and Cosmetic Act.

(f) Registration of Foreign Sellers. Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Food and Drug Administration the name and place of business of the establishment and the name of the United States agent for the establishment.

(g) Suspension of Importation. Importations of a specific prescription drug or importations by a specific importer under subsection (b) of this section shall be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Food and Drug Administration determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b) of this section.

(h) Approved labeling. The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

(i) Definitions. For purposes of this Section—

(1) The term "importer" means a pharmacist or wholesaler.

(2) The term "pharmacist" means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

(3) The term "prescription drug" means a drug subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act, other than—

(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

(C) an infused drug (including a peritoneal dialysis solution);

(D) an intravenously injected drug;

(E) a drug that is inhaled during surgery; or

(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) of this section has been determined by the Food and Drug Administration to pose a threat to the public health.

(4) The term "qualifying laboratory" means a laboratory in the United States that has been approved by the Food and Drug Administration for the purposes of this section.

(5) The term "wholesaler" means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A) of the Federal Food, Drug, and Cosmetic Act, but does not include a person authorized to import drugs under section 801(d)(1) of the Federal Food, Drug, and Cosmetic Act.

D. Issuance of Regulations Permitting Importation and Reimportation of Prescription Drugs from Canada into Illinois

In the alternative to the proposed regulation set forth in Section I.C of this Petition, Illinois requests that the Commissioner consult with the United States Trade Representative and the Commissioner of Customs, in accordance with the requirements of Section 804(b) of the FFDCA and the authority delegated to the Commissioner under Chapter 21, Section 5.10 of the Code of Federal Regulations, and promulgate regulations authorizing pharmacists and wholesalers to import and to reimport prescription drugs from Canada into Illinois, as a pilot program to test whether such importation and reimportation should be allowed nationwide. Illinois proposes the same regulatory text proposed in Section I.C of this Petition, except with the following language in place of Section 203.10(b):

(b) Pharmacists and wholesalers are permitted to import and to reimport prescription drugs from Canada into Illinois under the conditions and restrictions set forth in this section.

E. Issuance of Regulations Authorizing Limited Pilot Program in Illinois

In the alternative to the proposed regulation set forth in Sections I.C and I.D of this Petition, Illinois requests that the Commissioner consult with the United States Trade Representative and the Commissioner of Customs, in accordance with the requirements of Section 804(b) of the FFDCA and the authority delegated to the Commissioner under Chapter 21, Section 5.10 of the Code of Federal Regulations, and promulgate regulations authorizing a pilot program in Illinois under which pharmacists and wholesalers would be permitted to import prescription drugs from Canada into Illinois as part of a limited demonstration program, with sales to consumers limited to persons receiving medical insurance from Illinois (including state employees, retired state employees, teachers, state college employees, local governmental

employees, and wards of the state). Illinois proposes the same regulatory text proposed in Section I.C of this Petition, except with the following language in place of Section 203.10(b):

(b) Pilot Program in the State of Illinois—

(1) Pharmacists and wholesalers are permitted to import and to reimport prescription drugs from Canada into the State of Illinois under a pilot program operated by the State of Illinois, subject to the conditions and restrictions set forth in this subsection and subsections (c) through (i) of this section.

(2) Consumers eligible to purchase imported and reimported prescription drugs under the pilot program described in this subsection are limited to persons receiving medical insurance from the State of Illinois, including state employees, retired state employees, teachers, state college employees, local governmental employees, and wards of the State of Illinois.

(3) The State of Illinois, Office of Special Advocates for Prescription Drugs, in consultation with the Food and Drug Administration, will develop a preferred drug list detailing those drugs that can be safely obtained from Canadian sources. The list—

(A) will be comprised of predominately brand-name drugs for long-term usage;

(B) will include only drugs that can be obtained more cost-effectively from Canada than from the United States;

(C) will be subject to periodic review and update to ensure continued cost-savings; and

(D) will include only prescription drugs that can meet the safety and effectiveness standards set forth in subsection (c) of this section.

(4) The State of Illinois shall implement the following protections to ensure patient safety:

(A) Participants in the pilot program must first have an eligible prescription filled by an Illinois pharmacy with a 30-day supply before obtaining a refill for that drug through the importation program.

(B) The State of Illinois will implement a Primary Care Pharmacist model, whereby every participant in the pilot program shall have the opportunity to choose an Illinois pharmacist to coordinate and monitor his or her drug therapy.

(C) In collaboration with the University of Illinois College of Pharmacy, the State of Illinois will implement a monitoring program to evaluate the safety and efficacy of prescription drugs received by plan participants from all sources.

(D) The State of Illinois shall contract with a private entity to maintain a toll-free number with a pharmacist available 24 hours a day, 7 days a week, to answer any medication-related questions by plan participants.

(E) In addition to oversight by the State of Illinois, all pharmacists and wholesalers involved in filling prescriptions under the pilot program shall meet all

applicable licensing and regulation requirements for pharmacists and wholesalers of prescription drugs under the laws and regulations of Canada (for pharmacists and wholesalers located in Canada) or the United States (for pharmacists and wholesalers located in the United States).

(F) Prescriptions shall be dispensed under the pilot program only pursuant to a valid prescription.

(5) The State of Illinois shall submit annual reports to the Food and Drug Administration and the United States Department of Health and Human Services regarding the effectiveness and cost-savings of the program.

F. Issuance of Regulations Granting Waiver to United States Residents

In the alternative to the proposed amendment and regulations set forth in Sections I.B through I.E of this Petition, Illinois requests that the Commissioner promulgate regulations, in accordance with Section 804(j) of the FFDCA and the authority delegated to the Commissioner under Chapter 21, Section 5.10 of the Code of Federal Regulations, granting a waiver to residents of the United States to import or to reimport prescription drugs from Canada for personal use. Illinois proposes the following regulation:

Waiver for residents to import or to reimport prescription drugs for personal use.

(a) The residents of the United States are granted a waiver of the prohibition of importation of prescription drugs, and are permitted to import and to reimport prescription drugs from Canada into the United States, subject to the conditions and restrictions set forth in this section.

(b) No prescription drug may be imported or reimported under this section other than a prescription drug that—

(1) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

(2) is accompanied by a copy of a valid prescription;

(3) is imported from Canada, from a seller registered with the Food and Drug Administration;

(4) is a prescription drug approved by the Food and Drug Administration under chapter V of the Federal Food, Drug, and Cosmetic Act; and

(5) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510 of the Federal Food, Drug, and Cosmetic Act.

G. Issuance of Regulations Granting Waiver to Illinois Residents

In the alternative to the proposed amendment and regulations set forth in Sections I.B through I.F of this Petition, Illinois requests that the Commissioner promulgate regulations, in accordance with Section 804(j) of the FFDCA and the authority delegated to the Commissioner under Chapter 21, Section 5.10 of the Code of Federal Regulations, granting a waiver to residents of the State of Illinois to import or to reimport prescription drugs from Canada for personal use, as a pilot program to test whether such a waiver should be granted nationwide.

Illinois proposes the following regulation:

Waiver for Illinois residents to import or to reimport prescription drugs for personal use.

(a) The residents of the State of Illinois are granted a waiver of the prohibition of importation of prescription drugs, and are permitted to import and to reimport prescription drugs from Canada into the State of Illinois, subject to the conditions and restrictions set forth in this section.

(b) No prescription drug may be imported or reimported under this section other than a prescription drug that—

(1) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

(2) is accompanied by a copy of a valid prescription;

(3) is imported from Canada, from a seller registered with the Food and Drug Administration;

(4) is a prescription drug approved by the Food and Drug Administration under chapter V of the Federal Food, Drug, and Cosmetic Act; and

(5) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510 of the Federal Food, Drug, and Cosmetic Act.

H. Issuance of Regulations Granting Waiver to Illinois Residents for Limited Pilot Program

In the alternative to the proposed amendment and regulations set forth in Sections I.B through I.G of this Petition, Illinois requests that the Commissioner promulgate regulations, in accordance with Section 804(j) of the FFDCA and the authority delegated to the Commissioner

under Chapter 21, Section 5.10 of the Code of Federal Regulations, granting a waiver to Illinois residents to import prescription drugs from Canada under a pilot program established by Illinois, with such waiver limited to residents receiving medical insurance from Illinois. Illinois proposes the following regulation:

Pilot program waiver for Illinois residents to import prescription drugs.

(a) The residents of the State of Illinois are granted a waiver of the prohibition of importation of prescription drugs, and are permitted to import and to reimport prescription drugs from Canada into the State of Illinois under a pilot program operated by the State of Illinois, subject to the conditions and restrictions set forth in this section.

(b) Persons permitted to import and to reimport prescription drugs under the pilot program described in this section are limited to residents receiving medical insurance from the State of Illinois, including state employees, retired state employees, teachers, state college employees, local governmental employees, and wards of the State of Illinois.

(c) No prescription drug may be imported or reimported under this section other than a prescription drug that—

(1) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

(2) is accompanied by a copy of a valid prescription;

(3) is imported from Canada, from a seller registered with the Food and Drug Administration;

(4) is a prescription drug approved by the Food and Drug Administration under chapter V of the Federal Food, Drug, and Cosmetic Act; and

(5) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510 of the Federal Food, Drug, and Cosmetic Act.

(d) The State of Illinois, Office of Special Advocates for Prescription Drugs, in consultation with the Food and Drug Administration, shall develop a preferred drug list detailing those drugs that can be safely obtained from Canadian sources. The list—

(1) will be comprised of predominately brand-name drugs for long-term usage;

(2) will include only drugs that can be obtained more cost-effectively from Canada than from the United States;

(3) will be subject to periodic review and update to ensure continued cost-savings; and

(4) will include only prescription drugs that can meet the safety and effectiveness standards set forth in section 505 of the Federal Food, Drug, and Cosmetic Act (including with respect to being safe and effective for the intended use of the prescription drug), in sections 501 and 502 of the Federal Food, Drug, and Cosmetic Act, and in all other applicable provisions of the Federal Food, Drug, and Cosmetic Act relating to the safety and effectiveness of prescription drugs.

(e) The State of Illinois shall implement the following protections to ensure patient safety:

(1) Participants in the pilot program must first have an eligible prescription filled by an Illinois pharmacy with a 30-day supply before obtaining a refill for that drug through the importation program.

(2) The State of Illinois will implement a Primary Care Pharmacist model, whereby every participant in the pilot program shall have the opportunity to choose an Illinois pharmacist to coordinate and monitor his or her drug therapy.

(3) In collaboration with the University of Illinois College of Pharmacy, the State of Illinois will implement a monitoring program to evaluate the safety and efficacy of prescription drugs received by plan participants from all sources.

(4) The State of Illinois shall contract with a private entity to maintain a toll-free number with a pharmacist available 24 hours a day, 7 days a week, to answer any medication-related questions by plan participants.

(5) In addition to oversight by the State of Illinois, all pharmacists and wholesalers involved in filling prescriptions under the pilot program shall meet all applicable licensing and regulation requirements for pharmacists and wholesalers of prescription drugs under the laws and regulations of Canada (for pharmacists and wholesalers located in Canada) or the United States (for pharmacists and wholesalers located in the United States).

(6) Prescriptions shall be dispensed under the pilot program only pursuant to a valid prescription.

(f) The State of Illinois shall submit annual reports to the Food and Drug Administration and the United States Department of Health and Human Services regarding the effectiveness and cost-savings of the program.

II. STATEMENT OF GROUNDS

A. Interest of the Petitioner

Illinois provides medical insurance, including prescription drug coverage, to more than 400,000 state employees, retirees, teachers, state college employees, local governmental employees, and wards of the state. Illinois expends more than \$340 million per year on

prescription drugs for employees and retirees alone, and more than \$1.8 billion on prescription drugs for all of its health programs combined. The demand for prescription drugs by Illinois plan participants and the costs of such drugs have increased steadily, with the costs to Illinois increasing at the rate of approximately 15% each year for the past five years. That trend is expected to continue as pharmacological advances provide new and better solutions to manage acute and chronic illnesses, and as the population ages.

In an effort to reduce the enormous financial burden of its prescription drug coverage, without reducing benefits and without creating risks to public health and safety, Illinois has designed a prescription drug importation plan that it now seeks to put into operation. The Illinois plan is designed to allow plan participants to purchase safe, regulated prescription drugs imported from Canada at prices well below what the plan members and Illinois must pay in the United States for identical drugs. The plan would be strictly voluntary, and would operate under one of two models corresponding to Section 804(b) and 804(j) of the FFDCA, respectively. Under the first model (the "Resale Model"), several alternative versions of which are set forth in Sections I.C. through I.E of this Petition,¹ pharmacists and wholesalers would import eligible prescription drugs from Canada, and plan participants would purchase their prescription drugs from the pharmacists and wholesalers. Under the second model (the "Direct Purchase Model"), several alternative versions of which are set forth in Sections I.F through I.H of this Petition,² plan participants would receive a waiver to purchase eligible prescription drugs for personal use

¹ Section I.C is a nationwide version of the Resale Model, Section I.D is limited to ~~the~~ Illinois as a pilot program to determine whether a nationwide Resale Model is appropriate, and Section I.E is a limited pilot program with participation confined to individuals insured through Illinois, such as state employees and retirees.

² Section I.F is a nationwide version of the Direct Purchase Model, Section I.G is limited to Illinois as a pilot program to determine whether a nationwide Direct Purchase Model is appropriate, and Section I.H is a limited pilot program with participation confined to individuals insured through Illinois, such as state employees and retirees.

directly from Canadian pharmacies with the assistance of a Pharmacy Benefits Manager or similar entity under contract with Illinois.

The limited pilot program versions of both the Resale Model and the Direct Purchase Model, set forth in sections I.E and I.H of this Petition, incorporate numerous controls to protect the health and safety of plan participants. Under both models, importation would be limited to drugs identified as safe by the Illinois Office of Special Advocates for Prescription Drugs, in consultation with the Food and Drug Administration ("FDA"). Both models include a "no first fill" policy requiring plan participants to purchase the first 30-day supply of any eligible prescription drug from an Illinois pharmacy before buying imported prescription drugs. Additionally, both models require Illinois to implement an ingredient and quality assurance testing program, as well as a Primary Care Pharmacist model allowing every plan participant to have an Illinois pharmacist coordinate and monitor his or her drug therapy. All of these controls are in addition to the numerous safety, reporting, testing, registration, and recordkeeping requirements set forth in Section 804(b) and (j) of the FFDCA, discussed in greater detail below, which are incorporated into every version of both the Resale Model and the Direct Purchase Model. The cost savings to Illinois, its residents and its taxpayers from either version of the proposed importation plan are projected to be up to \$90 million a year.

B. Governing Statutes and Regulations

Section 804 of the FFDCA, as amended by the MPDM Act, provides the appropriate statutory framework for the Commissioner to promulgate regulations authorizing importation of prescription drugs from Canada under either the Resale Model or the Direct Purchase Model. Importation and reimportation of prescription drugs in the United States is governed by Chapter VIII of the FFDCA, 21 U.S.C. §§ 381 *et seq.* The provision governing reimportation, 21 U.S.C.

§ 381(d)(1), prohibits reimportation of prescription drugs by anyone other than the manufacturer, with two exceptions. It states: *'Except as provided in paragraph (2) and section 384 of this title*, no drug subject to section 353(b) of this title or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug." The first exception, 21 U.S.C. § 381(d)(2), states that the Secretary "may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care." The second exception is Section 804, to be codified as amended at 21 U.S.C. § 384.³

Section 804(b) provides: "The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States." (Exh. 1, at § 804(b)). "Prescription drugs" is defined to include regulated drugs subject to Section 503(b) of the FFDCA, other than controlled substances, biological products, infused drugs, intravenously injected drugs, drugs inhaled during surgery, and certain classes of parenteral drugs. (*Id.*, at § 804(a)(3)). Section 804(c) identifies various health and safety limitations that must be included in any regulations promulgated pursuant to Section 804(b), including (1) compliance with Sections 501, 502, and 505 of the FFDCA; (2) information and recordkeeping requirements; and (3) testing requirements. (*Id.*, at § 804(c), (d)(1), (e)). The compliance, information, recordkeeping, and testing requirements are reflected in subsections (c), (d), and (e) of the regulation proposed in Section I.C of this Petition.

³ Section 1121 of the MPDM Act amended an earlier version of Section 804 of the FFDCA, created by the Medicine Equity and Drug Safety Act of 2000 and codified at 21 U.S.C. § 384. Because the MPDM Act and its revisions to Section 804 have not yet been codified as of the filing of this Petition, a copy of Section 1121 of the MPDM Act with the amended version of Section 804 is attached hereto as **Exhibit 1**.

In addition to Section 804(b)'s assignment of regulatory duties, Section 804(j) grants authority to the Secretary of Health and Human Services (and to the Commissioner by redelegation under 21 C.F.R. § 5.10) to waive the prohibition on personal importation of prescription drugs. With respect to enforcement actions against individuals, Section 804(j)(1) directs the Secretary to "focus enforcement on cases in which the importation by an individual poses a significant threat to public health," and to "exercise discretion to permit individuals to make such importation in circumstances where—(i) the importation is clearly for personal use; and (ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual." (*Id.*, at § 804(j)(1)). Furthermore, Section 804(j)(2) provides that the Secretary "may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate." (*Id.*, at § 804(j)(2)). More particularly, Section 804(j)(3) directs that the Secretary "shall by regulation grant individuals a waiver to permit individuals to import into the United States [from Canada] a prescription drug that" complies with various identified requirements, which are reflected in subsection (b) of the regulation proposed in Section I.E of this Petition. (*Id.*, at § 804(j)(3)).

None of the provisions of Section 804 take effect until a certification is made to Congress in accordance with Section 804(l) of the FFDCA. Section 804(l) states, in relevant part:

(1) Commencement of Program.—This section shall become effective only if the Secretary certifies to the Congress that the implementation of this section will—

(A) pose no additional risk to the public's health and safety; and

(B) result in a significant reduction in the cost of covered products to the American consumer.

(*Id.*, at 804(l)(1)).

As of the filing of this Petition, no certification has yet been made to Congress under Section 804(l)(1), and no regulations have been promulgated implementing Section 804 of the FFDCA. The existing regulations under Chapter VIII of the FFDCA continue to prohibit the reimportation of prescription drugs by anyone other than the manufacturer, except for emergency medical care. Chapter 21, Section 203.10 of the Code of Federal Regulations provides: "No prescription drug or drug composed wholly or partly of insulin that was manufactured in a State and exported from the United States may be reimported by anyone other than its manufacturer, except that FDA may grant permission to a person other than the manufacturer to reimport a prescription drug or insulin-containing drug if it determines that such reimportation is required for emergency medical care." 21 C.F.R. § 203.10. Requests for an emergency medical care exception are handled by an application process at the district office level of the FDA. *See* 21 C.F.R. §§203.11-203.12.

The Secretary's authority to make a certification to Congress under Section 804(l)(1) of the FFDCA is redelegated to the Commissioner under 21 C.F.R. § 5.10. Therefore, upon the Commissioner's certification to Congress that implementation of Section 804 will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer, Section 804 will take effect. The Commissioner will then have the authority under Section 804(b) to promulgate regulations authorizing pharmacists and wholesalers to import prescription drugs from Canada, enabling Illinois to implement the Resale Model of its plan. Alternatively, the Commissioner will have the authority under Section 804(j) to grant a regulatory waiver to Illinois residents allowing personal importation of prescription drugs from Canada into the United States, enabling Illinois to implement the Direct Purchase Model of its plan.

C. The Commissioner Has the Discretion to Adopt a Pilot Program in Illinois

This Petition offers a range of alternative options to effect an importation plan consistent with the statutory terms of Section 804. For example, the Petition offers three alternative versions of the Resale Model. The regulation proposed in Section I.C of this Petition would permit importation by pharmacists and wholesalers into the United States generally, whereas the regulation proposed in Section I.D would permit importation only into Illinois, as a pilot program to determine whether nationwide importation is appropriate. If the Commissioner determines that a more limited trial program is needed before allowing general importation into the United States or Illinois, the regulation proposed in Section I.E would permit limited importation by pharmacists and wholesalers into Illinois for a pilot program to be operated by Illinois, confined to consumers who receive medical insurance through Illinois, such as state employees and retirees.

Section 804 unambiguously authorizes a limited pilot program of this type. Although Section 804(b) provides that the Secretary "shall promulgate" regulations permitting importation from Canada after certification under Section 804(l), the provision then confers wide discretion upon the Secretary (and, by redelegation, upon the Commissioner) in formulating such regulations. Section 804(c)(3) provides that the regulations shall "contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs." Thus, if the Commissioner determines that a pilot program is an appropriate means to protect public health or to facilitate the importation of prescription drugs, Section 804 authorizes a pilot program regulation.

Sections I.F through I.H of this Petition offer three similar alternative versions of the Direct Purchase Model. Section I.F is a nationwide waiver for United States residents, whereas Section I.G is limited to Illinois residents, as a pilot program to determine whether nationwide waiver is appropriate. Section I.H is a more limited pilot program, confined to Illinois residents who receive medical insurance through Illinois, such as state employees and retirees. Section 804(j)(2)(A) clearly contemplates limited waivers, as it authorizes waivers "by regulation or on a case-by-case basis ... under such conditions as the Secretary determines to be appropriate." Moreover, Section 804(j)(3)(F) provides that a regulatory waiver shall include "such other conditions as the Secretary determines to be appropriate to ensure public safety." Again, therefore, if the Commissioner determines that a limited pilot program is the most appropriate way to exercise waiver authority under Section 804(j), the statutory language permits a limited regulatory waiver for Illinois to implement a pilot program.

Likewise, the FDA is expressly authorized by the FFDCA to cooperate with state officials, such as the State of Illinois, Office of Special Advocates for Prescription Drugs, in administering the provisions of the FFDCA. Section 702(a) of the FFDCA, 21 U.S.C. § 372(a), states in relevant part: "(a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department." Thus, the FDA is permitted to assign certain oversight responsibilities for the proposed pilot program to Illinois, as contemplated by the regulations proposed in Section I.E and I.H of this Petition.

D. Importation of Prescription Drugs from Canada Is Safe

Whether employed generally or only on a limited pilot program basis, importation of prescription drugs from Canada would pose no additional risk to the public's health and safety.

The Office Of Special Advocates For Prescription Drugs, Illinois Department Of Central Management Services (the "Special Advocates") has conducted a lengthy and far-reaching analysis of the safety and feasibility issues surrounding importation of prescription drugs from Canada. A copy of the Special Advocates' October 27, 2003 report, "Report On Feasibility Of Employees And Retirees Safely And Effectively Purchasing Prescription Drugs From Canadian Pharmacies" (the "Report"), is attached hereto as **Exhibit 2** and is adopted and incorporated herein. The Report was prepared after extensive research and analysis of the regulatory practices of Canada and the United States, solicitation of the views of major organizations and associations within the United States pharmaceutical industry, and a fact-finding visit to several of Canada's major pharmaceutical providers. (Exh. 2: Report, at 1-2, 8-9). Numerous experts participated in the Special Advocates' investigation and analysis, including the Chief Medical Officer of Illinois, multiple doctors of pharmacy and registered pharmacists, and various representatives of the Illinois Department of Public Health and the Illinois Department of Professional Regulation. The names and credentials of the participants in the Special Advocates' investigation, and their research methods and design, are identified on pages 8-10 of the Report.

Since publication of the Report, Illinois has also consulted various independent experts on the safety and feasibility of importing prescription drugs from Canada. The independent experts consulted by Illinois include Professor Alan Sager, Ph.D., a professor of health services at the Boston University School of Public Health, and Randall L. Stephanchew, a former Drug Specialist and Acting Operational Manager with the Health Protection Branch of Health Canada, and a licensed Canadian pharmacist. The affidavits of these independent experts are attached hereto as **Exhibits 3 and 4** and are adopted and incorporated herein. The Special Advocates and the independent experts all agree that Canada has a secure and effective regulatory regime that

successfully protects the safety of its prescription drugs, that drugs purchased from Canada under the Canadian regulatory regime are at least equal in safety and quality to drugs purchased within the United States, and that the regulated importation of drugs from Canada into the United States would not pose any increased risk to the public's health and safety. This section summarizes the findings and conclusions of the Report and the independent experts' affidavits.

The Canadian regulatory system, though not identical to the United States, provides equivalent protections to ensure the safety of prescription drugs at every level. (Exh. 2: Report, at 2-3, 11-18; Exh. 4: Stephanchew Aff., ¶¶8-17). Canada regulates prescription drugs through its Food and Drug Act and Food and Drug Regulations, relevant portions of which are attached hereto as **Exhibits 5 and 6**, and are adopted and incorporated herein. All prescription drugs sold in Canada must be approved by Health Canada's Therapeutic Product Directorate (the "TPD") under a stringent approval process comparable in rigorousness to FDA approval. (Exh. 2: Report, at 13, 18; Exh. 4: Stephanchew Aff., ¶12; Exh. 5: Food and Drugs Act, § 30(o); Exh. 6: Regulations, §§ C.08.001-C.08.018). Fundamentally, a manufacturer must present substantive scientific evidence and clinical studies proving a product's safety, efficacy, and quality. (Exh. 2: Report, at 18; Exh. 4: Stephanchew Aff., ¶12; Exh. 6: Regulations, §§ C.08.002-C.08.009). As with FDA approval, TPD approvals are manufacturer-specific and product-specific, including factors like manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure systems, appearance, purity, and labeling. (Exh. 4: Stephanchew Aff., ¶13; Exh. 6: Regulations, § C.08.002(2)). For second entry products, applicants must demonstrate functional equivalence to the original marketed product. (Exh. 6: Regulations, § C.08.002.1). Canadian bioequivalence standards are very similar to FDA standards. (*Id.*).

Like the United States, Canada strictly prohibits sales of drugs that were manufactured, prepared, preserved, packaged, or stored under unsanitary conditions and drugs that are adulterated. (Exh. 5: Food and Drugs Act, §§8-15). Also like the United States, Canada imposes rigorous requirements for licensing, manufacturing, packaging, testing, recordkeeping, and labeling. (Exh. 2: Report, at 18; Exh. 5: Food and Drugs Act, § 30; Exh. 6: Regulations, §§ C.01.003-C.01.013, C.01.014-C.01.014.7, C.01.016-C.01.017, C.01.021-C.01.027, C.01.028-C.01.035, C.01.040.2, C.01.061-C.01.062, C.01.068-C.01.069, C.01A.001-C.01A.019, C.02.002-C.02.030, C.08.001-C.08.018). Canada, like the United States, requires manufacturers to comply with strict Good Manufacturing Practices ("GMP"). (Exh. 4: Stephanchew Aff., ¶13; Exh. 6: Regulations, §§ C.02.002-C.02.030). Many brand name prescription drugs sold in Canada are actually manufactured in the United States in FDA approved facilities. (Exh. 2: Report, at 13). All drugs, whether manufactured in Canada or elsewhere, must be manufactured in facilities approved by the TPD. (Exh. 2: Report, at 13-14; Exh. 6: Regulations, § C.08.002).

The Canadian GMP requirements for testing, warehousing, and storage of pharmaceuticals are comparable to the United States. (Exh. 2: Report, at 15, 36-42; Exh. 4: Stephanchew Aff., ¶13; Exh. 6: Regulations, §§ C.02.001-C.02.030). Both require quality control units staffed by trained personnel to test and inspect the product and its packaging. (*Id.*). Both require segregation of untested, tested, and approved or rejected prescription drugs. (*Id.*). Both require testing of raw materials before production and testing of the finished product after production and in subsequent distribution. (*Id.*). Both countries include similar directions for storing the prescription drug under appropriate conditions of temperature, humidity, lighting, stock rotation, and sanitation. (*Id.*). Both have similar building design and construction features, including requirements for ventilation, air filtration, heating, cooling, and sanitation. (*Id.*). Both

have comparable requirements for production and storage, equipment cleaning and maintenance, packaging, and recordkeeping. (*Id.*). Labeling requirements in Canada are similar to those in the United States. (Exh. 6: Regulations, §§ C.01.003-C.01.012).

Canada, like the United States, follows a "closed system" for the distribution of prescription drugs; from the manufacturer to the retailer, all points on the distribution chain are regulated. Once a drug is approved, the TPD issues a Drug Identification Number ("DIN") that allows a manufacturer to market the drug. (Exh. 2: Report, at 13; Exh. 4: Stephanchew Aff., ¶14; Exh. 6: Regulations, §§ C.01.014-C.01.014.7). The DIN is similar to the National Drug Code ("NDC") number issued in the United States. (Exh. 2: Report, at 13). The Canadian and United States "closed systems" have nearly identical controls and recordkeeping to verify where the drugs have been, the conditions under which they have been stored, and whether or not there has been tampering or contamination. (Exh. 6: Regulations, §§ C.01.014-C.014.7, C.02.020-C.02.028). Once a drug reaches the pharmacy, regulation of dispensation to patients is regulated by provincial law in Canada, just as it is regulated by state law in the United States.

Pharmacy practice under provincial law in Canada is equal or superior to pharmacy practice in the United States. (Exh. 2: Report, at 2-3, 14-15; Exh. 4: Stephanchew Aff., ¶15). The Special Advocates' investigation included a comparison of pharmacy practices in the Canadian provinces of Manitoba and Ontario with pharmacy practices in Illinois. Like the United States, the Canadian pharmacy system has both internal and external monitoring systems in place. (Exh. 2: Report, at 14). The pharmacist in charge is required to maintain, monitor, and supervise staff and their professional practices, and to ensure compliance with the provincial laws. (*Id.*). All pharmacies adhere to quality control measures in procurement, dispensing, and counseling to enhance safety. (*Id.* at 14-15). Computer checking of patient histories and

prescriptions is used to identify and trigger warnings on potential drug therapy problems, including drug-drug interactions, drug-allergy checks, and under/over dose. (*Id.*). Bar code technology is used to achieve a high degree of accuracy. (*Id.*). Provincial agency inspectors conduct regular inspections of pharmacies and evaluate all consumer complaints. (*Id.* at 14). A comparison of the inspectors' scope of inspection indicates that pharmacy inspectors in Canada operate under a set of standards as strict as those maintained by the Office of Drug Compliance in Illinois. (*Id.*). The reporting of internal process errors was found to be more rigorous in Canada than in the United States. (*Id.*). A detailed record of consumer complaints and follow-up is maintained, similar to the practice in Illinois. (*Id.* at 15-16). The educational requirements, examinations, registration and licensure procedures, and professional regulation of pharmacists in Canada is as rigorous as in the United States. (*Id.* at 16-18).

Furthermore, the Canadian system of pricing and distribution is less likely to foster drug counterfeiting. In the United States, drug manufacturers distribute their products through wholesalers to retailers or mail order pharmacies. Because the manufacturers ship in large quantities, it is common practice for the drugs to be repackaged by independent entities, wholesalers, or distribution centers. (Exh. 2: Report, at 12-13). The FDA has reported that the repackaging of drugs in the United States is a point of weakness that presents an opportunity for the introduction of counterfeit drugs. (*Id.*, citing *FDA Counterfeit Drug Task Force Interim Report: Safe and Secure*, at 9 (U.S. Department of Health and Human Services, October 2003)). The FDA estimates that the number of open counterfeit drug cases has more than tripled over the past six years. (*Id.* at 12, citing *New FDA Initiative to Combat Counterfeit Drugs*, <http://www.fda.gov/oc/initiatives/counterfeit/backgroundunder.htm>). Aggravating the problem is the high variability of price between different classes of trade in the United States (Hospitals, Retail

Pharmacies, Government Owned Facilities, Physician Offices, etc.), which has resulted in a secondary market that offers opportunities for diversion and counterfeiting while creating situations where a chain of custody for prescription drugs cannot be established. (*Id.* at 13).

In Canada, by contrast, the government negotiates prices as a part of the approval process, wholesalers acquire the product at the negotiated price, and the product is sold to retailers at a small premium. (Exh. 2: Report, at 13). Different classes of trade pay essentially the same price for the same prescription drugs, reducing the secondary market problem. (*Id.*). The secondary market in Canada is confined to small retail transactions between licensed pharmacies. (*Id.*). Similarly, manufacturers sell drugs to Canadian pharmacies in "unit of use" sealed packages, which the pharmacies dispense directly to customers. (*Id.* at 2, 13). These "unit of use" sealed packages significantly reduce opportunities for diversion, counterfeiting, and pharmacist error, while drugs in the United States can move through multiple vendors and be resold and repackaged several times before reaching the patient. (*Id.*).

Additionally, the price reductions achieved through the importation of Canadian prescription drugs would yield significant public health benefits in the United States. The United States presently has the highest prescription drug prices in the world, and those prices continue to rise. (Exh. 3: Sager Aff., at 3-6). As a result, many patients do not fill their doctors' prescriptions, and others do not even go to the doctor because they know they cannot afford the cost of prescription drugs. (*Id.*, at 7-8). Thus, enabling patients to purchase imported prescription drugs at lower prices would reduce avoidable death, disability, illness, and pain owing to patients' inability to afford needed medications. (*Id.*, at 7). Likewise, the prohibition on importation combined with high prescription drug prices has created an illegal, unregulated black market for prescription drugs. (*Id.*, at 8-9). The evidence of harm or increased risk

associated with the importation of Canadian prescription drugs is minimal, but what evidence exists is attributable to the illegality of importation and the resulting black market status of the prescription drug import market. (*Id.*). Conversely, if legal importation were permitted, drug imports would be regulated to eliminate the types of risks identified in connection with black market imports. (*Id.*).

The Canadian regulatory regime at all levels—from approval and manufacturing through testing, storage, distribution, and sale—is secure, safe, and effective. Drugs purchased and imported from Canada are at least equal in safety and quality to domestic prescription drugs, having one of the best safety records in the world. (Exh. 4: Stephanchew Aff., ¶15). Accordingly, the regulated importation of prescription drugs from Canada into the United States would not pose any increased risk to the public's health and safety.

E. The Illinois Proposals Incorporate Additional Safeguards To Protect Public Safety

In addition to the inherent safety measures and regulatory controls found in the Canadian system, the proposals set forth in this Petition incorporate numerous additional safety measures to ensure public health and safety in the importation of prescription drugs from Canada. The three alternative proposals for importation under the Resale Model—set forth in Sections I.C and I.E of this Petition—incorporate a series of reporting, testing, and recordkeeping requirements mandated by Section 804 of the FDCA. Under all three proposals, every importer would be required to submit documentation to the FDA regarding the name and quantity of active ingredients of imported drugs, dosage, date of shipment, quantity shipped, point of origin and destination, price, original source and quantity, lot or control number, identity of the importer, chain of custody, testing, and certification of approval for marketing and labeling. Importers would also be required to test each batch of all initial imports and a statistically valid sample of

all subsequent imports in qualifying laboratories for authenticity and degradation. All foreign sellers of prescription drugs would also be obligated to register with the FDA.

Under the Direct Purchase Model—set forth in Sections I.F through I.H of this Petition—the FDA would grant a regulatory waiver to Illinois residents under Section 804(j) of the FFDCA rather than promulgating regulations authorizing importation by pharmacies and wholesalers under Section 804(b). In place of the reporting, testing, recordkeeping, and packaging requirements for importers, therefore, the Direct Purchase Model incorporates additional safety precautions directed to personal use. These precautions are in accordance with Section 804(j), and include limitation of imports to a 90-day supply for personal use and not for resale, requirement of a valid prescription, importation from Canada by sellers registered with the FDA, approval by the FDA under Chapter V of the FFDCA, and importation in the form of a final finished dosage manufactured in an establishment registered under Section 510 of the FFDCA.

Finally, whether the Commissioner chooses the Resale Model or the Direct Purchase Model, both proposals for a limited pilot program in Illinois—set forth in Sections I.E and I.H of this Petition—include additional safety features recommended by the Special Advocates. The proposed Illinois pilot program would require the Special Advocates, in consultation with the FDA, to develop a preferred drug list detailing those drugs that can be safely obtained from Canadian sources, comprised primarily of brand-name drugs for long-term usage that can meet safety and effectiveness standards. Illinois would follow a "no first fill" policy requiring participants to have an eligible prescription filled by an Illinois pharmacy with a 30-day supply before obtaining a refill through the importation program. A Primary Care Pharmacist model would be implemented so that every participant in the pilot program has the opportunity to choose an Illinois pharmacist to coordinate and monitor his or her drug therapy. Illinois would

contract with a private entity to establish a toll-free number with a pharmacist available 24 hours a day, 7 days a week to answer any medication-related questions by plan participants. Illinois would also implement its own monitoring requirements to independently verify safety and efficacy of imported prescription drugs, and would submit annual reports to the FDA regarding the effectiveness and cost-savings of the pilot program. Prescriptions would, of course, only be dispensed pursuant to a valid prescription.

Standing alone, the proven safety and effectiveness of the Canadian regulatory regime establishes that the importation of prescription drugs from Canada would not give rise to any new public health or safety risks. The various additional safeguards set forth in the Illinois proposals provide further confirmation that authorizing importation and reimportation of Canadian drugs under one or more of the proposals would not endanger public health and safety in any way. The drugs are safe in Canada, and the Illinois proposals adopt numerous protections to ensure that the drugs will remain safe when they are imported into the United States.

F. Importation of Prescription Drugs from Canada Under the Illinois Plan Results In Significant Cost Reductions

Prescription drugs purchased from Canadian sources are generally less expensive—often substantially less expensive—than chemically identical drugs purchased in the United States. Canadian pharmaceutical pricing, and particularly the centralized negotiation of drug prices by the Canadian government, is a major factor contributing to lower costs. In addition to reviewing safety and feasibility issues, the Special Advocates' Report also examined in detail the question of cost savings from importation of Canadian prescription drugs. (Exh. 2: Report, at 19, 79-81). The Report concluded that if all eligible prescriptions for Illinois employees and retirees were filled through Canadian pharmacies, the total annual savings would be \$90.7 million. (*Id.* at 19, 80). Initial savings, of course, would likely be lower, as it is unlikely that all Illinois employees

and retirees would immediately choose to fill all eligible prescriptions through Canadian pharmacies. In any event, however, Illinois consumers could expect to save tens of millions of dollars every year through the importation of Canadian prescription drugs. As confirmed by a review of the Report's methodology, these cost savings are not unique to Illinois. If importation of prescription drugs from Canada were implemented at the national level, American consumers would achieve a significant reduction in the cost of prescription drugs as a result of importation.

The Special Advocates' analysis reviewed the top 400 line items of brand name drugs by expense from prescription claims by Illinois employees and retirees participating in the state's non-managed Quality Care Health Plan. (Exh. 2: Report, at 79-81). The 400 line items accounted for 192 unique brand name drugs, and amounted to a projected annual expenditure of \$195.1 million. (*Id.* at 79). From this list, the Special Advocates deleted items deemed not suitable for importation from Canada, such as antibiotics and controlled substances. (*Id.*). The deletions resulted in a list of 232 line items (92 brand names), carrying a projected annual expenditure of \$152 million, or \$147 million in net costs after rebates. (*Id.*). The domestic prices of the eligible prescription drugs on the list were then compared with the prices for identical drugs in Canada, obtained from Canadian price lists. (*Id.*).

At Canadian prices (converted from Canadian dollars to U.S. dollars), the annualized costs of the 232 line items would have been \$90 million rather than \$147 million, for a net savings of \$57 million or 39%. (*Id.*). Subtracting \$2 million in implementation costs for the Primary Care Pharmacist model, net savings just on the 232 line items would be \$55 million. (*Id.*). Of those savings, \$20.7 million would be passed on directly to Illinois consumers through waived co-payments, while the remainder would be savings to the taxpayers of Illinois. (*Id.*). Those amounts are just the savings for a limited number of line items on the non-managed care

plan. The 232 selected line items account for only 67% of the total prescription drug expenditures under the non-managed care plan, so actual annual savings on the non-managed care plan alone could be even higher than \$55 million. (*Id.* at 80). Assuming an equivalent rate of savings on the Illinois managed care plans, the Special Advocates estimates potential savings from importation to the managed care plans would be \$37 million. (*Id.*). Subtracting \$1.3 million towards implementation of the Primary Care Pharmacist model, net savings to the managed care plans would be \$35.7 million, for a total projected savings of \$90.7 million. (*Id.*). That assumes importation of all eligible prescription drugs, however, so Illinois would expect its actual initial savings to be lower. Savings would increase as participation increases.

These projections do not assume any special pricing arrangements or negotiating power on the part of Illinois. The savings estimates are premised on retail Canadian price lists, without any negotiated savings or special volume discounts. It is likely, of course, that Illinois would be able to negotiate favorable discounts from Canadian sellers based on the volume of annual purchases by Illinois plan participants. Even without such discounts, however, potential annual savings of more than \$90 million represent a significant cost reduction to Illinois consumers. Likewise, a projected annual savings rate of 39% on prescription drugs unquestionably represents a significant reduction in cost to the American consumer. If importation were permitted nationwide, the cost savings would likewise increase exponentially. Projected savings from nationwide importation of prescription drugs at Canadian prices could total \$59.7 billion or more, with substantial, identifiable savings in every state. (Exh. 3: Sager Aff., at 10-11).

III. ENVIRONMENTAL IMPACT STATEMENT

The requested action will not result in the introduction of any substance into the environment, and is categorically excluded under 21 C.F.R. § 25.30.


IV. CONCLUSION

The rising tide of prescription drug prices represents an urgent problem for Illinois consumers and consumers nationwide, a problem requiring immediate attention. Regulated importation of Canadian prescription drugs represents an effective means of dramatically reducing the cost of prescription drugs, without compromising patient safety or public health. Accordingly, for the health and benefit of American consumers, the Commissioner should make a Section 804(l) certification to Congress and promulgate regulations authorizing the importation of prescription drugs from Canada under one or more of the proposals identified in this Petition.

V. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and view on which the Petition relies, and that it includes representative data and information known to the petitioner, none of which is unfavorable to the Petition.

Respectfully submitted,
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